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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/564,744 | 03/03/2006 | Thomas J. Gardella | 00786/540002 | 1482 |

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| EXAMINER | |
|---|---|
| GUPTA, ANISH | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1654 | |

| NOTIFICATION DATE | DELIVERY MODE |
|---|---|
| 02/06/2009 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/564,744 | GARDELLA, THOMAS J. | |
| | Examiner | Art Unit | |
| | ANISH GUPTA | 1654 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *24 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) *2-5,7-12,14-16 and 24-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6,13 and 17-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11-29-07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election without traverse of Group I, claims 1-23, with the species of SEQ ID NO 13 in the reply filed on 9-24-08 is acknowledged.

A search was conducted to the species of SEQ ID NO 23, this was found to be free of the prior art. In accordance with markush practice, the search was extended to SEQ ID NO 16 and prior art was found that anticipated the claimed invention. Claims 1, 6 and 17-23 read on the prior art peptide.

Claims 2-5, 7-12, 14-16 and 24-36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species and Groups, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on Sept. 24, 2008.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 6, 13 and 17-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite, as one of the alternatives of the sequence, N- and C-derivatives thereof. First it is unclear if N- and C-derivatives only include modifications at the N and C terminal ends. Furthermore, it is unclear what modifications can be made in the sequence to render the PTH analog a derivative. The claims are therefore indefinite.

***Claim Rejections - 35 USC § 102***

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1 and 6 and 17-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Shimuzu et al. (J. of Biol. Chem.).

The claims are drawn to PTH analogs.

The reference teaches PTH analogs that contain aminoisobutyric acid substations into the PTH analogs (See page 49004). The reference specifically teaches modifications in the rat PTH analog. Rat PTH naturally as the sequence of the first fourteen amino acids as ala-val-ala-glu-ile-gln-leu-gln-leu-met-his-asn-har-ala-ly-trp (see page 49004). The reference teaches that Aib can be substituted in positions 1 and 3 of the rat sequence (see page 49006). The reference disclose the full length, truncated analogs of 1-21, 1-14, 11, 1-10, and 1-9 (see page 49006). The reference disclose labeling the peptide with I125 and chloramine T (see page 49004). This sequence meets the limitation of claim 6 of the instant application. Thus, the reference meets the limitations of the claims.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 6 and 17-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimuzu et al. (J. of Biol. Chem.) in view of Gardella et al. (WO2000/23594).

The claims are drawn to labeled PTH analogs.

The reference of Shimuzu et al. has been discussed supra. The difference between the prior art and the instant application is that the reference does not specifically teach a 99mTC labeled peptide.

However, The reference of Gardella et al. teach synthetic and/or recombinant biologically active peptide derivatives of PTH (1-14). The reference further teaches that one can determining rates of bone reformation and/or bone remodeling, comprising administering a labeled foma of (A) (labeled with a radiolabel (such as 99mTC), a fluorescent label, a bioluminescent label or a chemiluminescent label) and determining uptake of the polypeptides into the bone of said patient (See page 12). Therefore, it would be obvious to one of ordinary skill in the art to use 99mTC as a label for determining rates of bone refomation and/or bone remodeling. It is noted that the primary reference teaches labeling using 125I. However, it would have been obvious to substituted 125I with 99mTC because Gardella teaches the use of both 99mTC and 125I (see examples).

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application

claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 6 and 17-23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 7 and 23-29 of copending Application No. 10/484,080. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. Note that the patent application has been indicated as being allowed. Once this application has been given a number, this rejection will be changed form provisional to a non-provisional rejection.

The claims are drawn to labeled PTH analogs.

The US patent claims a biologically active peptide comprising a formula selected from:

(a) $X_{01}$ValX$_{02}$GluIleGlnLeuMetHisX$_{03}$X$_{04}$X$_{05}$X$_{06}$X$_{07}$ (SEQ ID NO. 1);

(b) fragments thereof, containing amino acids 1-10, 1-11, 1-12 or 1-13; or

(c) pharmaceutically acceptable salts thereof;

wherein:

$X_{01}$ is an α-helix-stabilizing residue, desaminoGly, desaminoSer or desaminoAla;

$X_{02}$ is an α-helix-stabilizing residue, Ala, or Ser;

$X_{03}$ is Ala, Gln or Asn;

$X_{04}$ is Arg, Har or Leu;

$X_{05}$ is an α-helix-stabilizing residue, Ala or Gly;

$X_{06}$ is an α-helix-stabilizing residue or Lys;

$X_{07}$ is an α-helix-stabilizing residue, Trp or His; and

wherein at least one of $X_{01}$, $X_{02}$, $X_{05}$, $X_{06}$ or $X_{07}$ is an α-helix-stabilizing residue; ~~and~~ wherein said α-helix-stabilizing amino acid is selected from the group consisting of Aib, ACPC (1-aminocyclopropylcarboxylic acid), DEG (diethylglycine) and 1-aminocyclopentanecarboxylic acid; and wherein said peptide is 20 amino acids or fewer in length.

The US patent specifically claims AibValAibGluIleGlnLeuMetHisGlnHarGlyLysTrp, in claim 7 and AibValAibGluIleGlnLeuMetHisAsnLeuGlyLysHis in claim 8. The sequence of AibValAibGluIleGlnLeuMetHisGlnHarGlyLysTrp meets the limitation of claim 6 of the instant application. Thus, the claimed peptides are not patentably distinct from the peptides claimed in US 10/484,080.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANISH GUPTA whose telephone number is (571)272-0965.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Anish Gupta/
Primary Examiner, Art Unit 1654